

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION

THIS DOCUMENT RELATES TO:
State of Iowa v. Abbott Laboratories, et al.

MDL No. 1456
Master File No.: 01-CV-12257-PBS
(original S. D. Iowa No. 4:07-cv-00461-
JAJ-CFB)

Judge Patti B. Saris

**ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC.
TO THE STATE OF IOWA'S COMPLAINT**

Defendant Merck & Co., Inc. ("Merck"), by its undersigned attorneys, hereby answers the State of Iowa's Complaint, dated October 9, 2007, as follows. Each allegation not expressly admitted is denied. To the extent that an allegation of the Complaint is untrue as to Merck, Merck in this Answer denies each such allegation without inquiry into the conduct of the numerous other defendants in this action.

1. Merck admits that the State of Iowa (the "State" or "Plaintiff") purports to bring this action as alleged in Paragraph 1 of the Complaint, but Merck denies that there is any basis for the State to do so and denies that the State is entitled to any relief.

2. To the extent the allegations in Paragraph 2 are directed at Merck, Merck denies each and every allegation of Paragraph 2.

3. To the extent the allegations in Paragraph 3 are directed at Merck, Merck denies each and every allegation of Paragraph 3.

4. To the extent the allegations in Paragraph 4 are directed at Merck, Merck denies each and every allegation of Paragraph 4.

5. Merck avers that it manufactures and markets brand drugs and lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. Merck admits that the markets for prescription drugs are complicated and otherwise denies the allegations of Paragraph 6.

7. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7.

8. To the extent the allegations of Paragraph 8 purport to summarize the State's reimbursement obligations under federal law, Merck denies that Plaintiff has fairly or accurately summarized them, and refers to the applicable statutes and regulations. Merck otherwise lacks knowledge or information sufficient to form a belief as to the allegations of Paragraph 8.

9. To the extent the allegations in Paragraph 9 are directed at Merck, Merck denies each and every allegation of Paragraph 9.

10. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 and the accompanying footnote, except that Merck admits that it has executed a rebate agreement with the Secretary of Health and Human Services ("HHS"), that it pays Medicaid rebates to Iowa, and that such rebates lower the price Iowa Medicaid pays for Merck's prescription drugs. To the extent the allegations in Paragraph 10 or its footnote purport to summarize statutes or regulations,

Merck refers to the statute or regulation for the complete and accurate terms and denies any characterizations thereof by Plaintiff.

11. To the extent the allegations in Paragraph 11 are directed at Merck, Merck denies them.

12. To the extent the allegations in Paragraph 12 are directed at Merck, Merck denies them.

13. To the extent the allegations in Paragraph 13 are directed at Merck, Merck denies them.

14. Merck admits that it voluntarily participates in the Iowa Medicaid program, but denies that it has violated any State or Federal law.

15. To the extent the allegations in Paragraph 15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

16. To the extent the allegations in Paragraph 16 are directed at Merck, Merck denies them.

17. To the extent the allegations in Paragraph 17 are directed at Merck, Merck denies them.

18. Merck admits that Exhibit B to the Complaint purports to identify the prescription drugs Plaintiff contends are at issue in this matter, but denies any liability to Plaintiff with respect to any such NDCs and denies that the allegations by Plaintiff for Merck drugs satisfy the applicable pleading standard. To the extent the allegations in Paragraph 18 are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a basis as to their truth.

19. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19. To the extent the allegations in Paragraph 19 purport to summarize statutes or regulations, Merck refers to the statutes or regulations for their complete and accurate terms and denies any characterizations thereof by Plaintiff.

20. To the extent that the allegations in Paragraph 20 are directed at Merck, Merck denies them, except Merck admits that it manufactures and sells prescription drugs and that it participates in the Iowa Medicaid Program.

21. Merck admits that it conducts business in the State of Iowa.

22-42. The allegations in Paragraphs 22 through 42 are directed to other Defendants and require no response from Merck. To the extent a response is deemed to be required, Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

43. Merck admits that it is a New Jersey corporation and that its business includes manufacturing and selling pharmaceuticals and that its principal place of business is Whitehouse Station, New Jersey.

44-54. The allegations in Paragraphs 44 through 54 are directed to other Defendants and require no response from Merck. To the extent a response is deemed to be required, Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

55-58. The allegations in Paragraphs 55 through 58 relate to unnamed parties or Doe Defendants and require no response from Merck. To the extent a response is deemed to be required, Merck avers that it has not conspired or participated in wrongful

acts with unnamed parties or Doe Defendants as alleged by Plaintiff in Paragraphs 55 through 58. Otherwise, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraphs 55 through 58.

59. Merck admits that the State seeks to bring this action as alleged in Paragraph 59, but Merck denies there is any basis for the State to do so and denies that the State is entitled to any relief.

60. Paragraph 60 states Plaintiff's legal conclusions as to which no response is required.

61. Paragraph 61 states Plaintiff's legal conclusion as to venue as to which no response is required. Merck avers that this matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407. Merck denies that it committed illegal actions or caused any damage to Plaintiff as alleged in the Complaint. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 61, and on that basis denies them.

62. Merck admits that Medicaid was established by Title XIX of the Social Security Act, Merck refers to the provisions of Title XIX for the complete and accurate terms of the statute, and denies any characterizations thereof by Plaintiff in Paragraph 62.

63. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, except Merck admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 purport to summarize statutes or regulations, Merck refers to each such statute or regulation for the complete and accurate terms thereof, and denies any characterizations by Plaintiff.

64. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64. To the extent the allegations in Paragraph 64 purport to summarize a statute, Merck refers to the statute for its complete and accurate terms, and denies any characterizations thereof by Plaintiff.

65. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 65. To the extent the allegations in Paragraph 65 purport to a summarize statute, Merck refers to the statute for its complete and accurate terms, and denies any characterizations thereof by Plaintiff.

66. Merck admits that national drug codes are assigned to prescription drugs. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66.

67. Merck refers to the referenced regulation for its complete and accurate contents, and denies any characterization thereof by Plaintiff. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67.

68. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 purport to summarize an OIG report, Merck refers to the report for its accuracy and content, and denies any characterizations thereof by Plaintiff.

69. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69. To the extent the allegations in Paragraph 69 purport to summarize statutes or regulations, Merck refers to the statutes or regulations

for their complete and accurate terms, and denies any characterizations thereof by Plaintiff thereof.

70. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70.

71. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 71 regarding the State's setting of reimbursement rates. Merck avers that for years, and at all times relevant to the Complaint, it has been widely understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

72. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 72 regarding the State's beliefs. Merck avers that for years, and at all times relevant to the Complaint, it has been widely understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

73. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 73. To the extent the allegations in Paragraph 73 or its subsections purport to summarize regulations, Merck refers to the regulations for their complete and accurate terms, and denies any characterizations thereof by Plaintiff.

74. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74.

75. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 75.

76. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76.

77. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 77.

78. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 78.

79. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 79.

80. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 80.

81. Merck admits that pricing compendia such as First DataBank and Medi-Span publish AWP's and FUL's. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81.

82. To the extent the allegations in Paragraph 82 are directed at Merck, Merck denies that it "purposefully and fraudulently conceal[s]" the "true prices" of its drugs. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82.

83. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83.

84. To the extent the allegations in Paragraph 84 are directed at Merck, Merck denies them. Merck specifically denies that it "fraudulently misrepresent[s]" its true prices or that it reports "false and inflated prices."

85. Merck denies that it has engaged in “unfair practices, deception, and fraud,” as alleged in Paragraph 85. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 85 and Exhibit A.

86. Merck denies engaging in “fraudulent practices,” as alleged in Paragraph 86. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86.

87. Merck denies the allegations of Paragraph 87 as to Merck and avers that, by federal statute and long-standing industry usage, WAC is a list price and does not include discounts, such as for prompt payment.

88. Merck denies the allegations of Paragraph 88 as to Merck and avers that by federal statute and long-standing industry usage, WAC is a list price and does not include discounts, such as for prompt payment.

89. Merck denies the allegations of Paragraph 89 as to Merck and avers that by federal statute and long-standing industry usage, WAC is a list price and does not include discounts, such as for prompt payment.

90. Merck denies the allegations of Paragraph 90 as to Merck and avers that by federal statute and long-standing industry usage, WAC is a list price and does not include discounts, such as for prompt payment.

91. Merck denies the allegations of Paragraph 91 as to Merck and avers that by federal statute and long-standing industry usage, WAC is a list price and does not include discounts, such as for prompt payment.

92. Plaintiff has not asserted FUL fraud claims as to Merck. To the extent the allegations in Paragraph 92 are directed to Merck, Merck denies them.

93. Merck denies the allegations of Paragraph 93 and avers that for years, and at all times relevant to the Complaint, it has been widely understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

94. Merck denies the allegations of Paragraph 94 as to Merck and avers that for years, and at all times relevant to the Complaint, it has been common knowledge and widely understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

95. To the extent the allegations in Paragraph 95 are directed at Merck, Merck denies them, except Merck admits that it has provided the WAC or catalog prices for its drugs to certain industry pricing compendia, as well as to its customers, and avers that publishers apply their own markups to the WAC list prices. Merck further avers that for years, and at all times relevant to the Complaint, it has been common knowledge and widely understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 95.

96. To the extent the allegations in Paragraph 96 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 96.

97. To the extent the allegations in Paragraph 97 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97.

98. To the extent the allegations in Paragraph 98 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 98. To the extent that Paragraph 98 purports to quote from an unidentified source, Merck refers to the referenced source for its complete and accurate content and denies any characterization thereof by Plaintiff.

99. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99.

100. To the extent the allegations in Paragraph 100 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 100.

101. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at Merck, Merck denies them. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a belief as to their truth.

102-108. The allegations in Paragraphs 102 through 108 relate to FUL and require no response from Merck because Exhibit B does not make any “FUL fraud” allegations as to any Merck drug. To the extent the allegations in Paragraphs 102 through 108 are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a belief as to their truth.

109. The allegations in Paragraph 109 require no response from Merck on the grounds that the Iowa SMAC claims have been dismissed by the Court.

110. To the extent the allegations in Paragraph 110 are directed at Merck, Merck denies them, except Merck admits that it has executed a rebate agreement with

HHS, and refers to that agreement and the referenced statute for the terms thereof and denies any characterization thereof by Plaintiff. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 110.

111. To the extent the allegations in Paragraph 111 are directed at Merck, Merck denies them, except Merck admits that it has executed a rebate agreement with HHS. Merck refers to the rebate agreement for its terms, and denies any characterizations thereof by Plaintiff.

112. To the extent the allegations in Paragraph 112 are directed at Merck, Merck denies them, except Merck admits that it has executed a rebate agreement with HHS. Merck refers to the rebate agreement for its terms, and denies any characterizations thereof by Plaintiff.

113. To the extent the allegations in Paragraph 113 are directed at Merck, Merck denies them, except Merck admits that it has executed a rebate agreement with HHS. Merck refers to the rebate agreement for its terms and denies any characterizations thereof by Plaintiff. Merck refers to the statute for its complete and accurate terms and denies any characterizations thereof by Plaintiff.

114. To the extent the allegations in Paragraph 114 are directed at Merck, Merck denies them. Merck refers to the referenced statute for its complete and accurate terms and denies any characterizations thereof by Plaintiff. Otherwise, Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 114.

115. To the extent the allegations in Paragraph 115 are directed at Merck, Merck denies them.

116. To the extent the allegations in Paragraph 116 are directed at Merck, Merck denies them, except Merck admits that Paragraph 116 purports to quote from a statute, Merck refers to the referenced statute for its complete and accurate terms and denies any characterizations thereof by Plaintiff.

117. To the extent the allegations in Paragraph 117 are directed at Merck, Merck denies them, except Merck admits that Paragraph 117 purports to quote from a model rebate agreement. Merck refers to the agreement for its complete and accurate terms and denies any characterizations thereof by Plaintiff.

118. To the extent the allegations in Paragraph 118 are directed at Merck, Merck denies them, except Merck admits that Paragraph 118 purports to quote from a statutory provision. Merck refers to the statute for its complete and accurate terms and denies any characterization thereof by Plaintiff.

119. To the extent the allegations in Paragraph 119 are directed at Merck, Merck denies them, except Merck admits that Paragraph 119 purports to quote from a statutory provision. Merck refers to the statute for its complete and accurate terms and denies any characterization thereof by Plaintiff.

120. To the extent the allegations in Paragraph 120 are directed at Merck, Merck denies them, except Merck that Paragraph 120 purports to quote from a statutory provision. Merck refers to the statute for its complete and accurate terms and denies any characterization thereof by Plaintiff.

121. To the extent the allegations in Paragraph 121 are directed at Merck, Merck denies them, except Merck admits that it has executed a rebate agreement with

HHS. Merck refers to the rebate agreement for its accurate and complete terms and denies any characterizations thereof by Plaintiff.

122. Merck admits that it pays statutory rebates to state Medicaid programs in an amount determined by HHS based on utilization data reported by the states. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 122.

123. To the extent the allegations in Paragraph 123 are directed at Merck, Merck denies them, except Merck admits that it has executed a rebate agreement with HHS. To the extent the allegations in Paragraph 123 refer to statutes or regulations, those sources speak for themselves, and Merck denies any characterizations thereof by Plaintiff.

124. To the extent the allegations in Paragraph 124 refer to statutes or regulations, those sources speak for themselves, and Merck denies any characterizations thereof by Plaintiff. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 124.

125. To the extent the allegations in Paragraph 125 refer to statutes or regulations, those sources speak for themselves, and Merck denies any characterizations thereof by Plaintiff.

126. To the extent the allegations in Paragraph 126 are directed at Merck, Merck denies them.

127. Merck admits that it offers discounts, including discounts for prompt payment, to certain of its customers. Merck further avers that the determination of Best Price is complex, varies drug by drug, and is made pursuant to statutes, regulations, and

regulatory guidance that have changed over time. Otherwise, to the extent the allegations in Paragraph 127 are directed at Merck, Merck denies them.

128. To the extent the allegations in Paragraph 128 are directed at Merck, Merck denies them. Merck refers to the Model Rebate Agreement for its complete and accurate contents and denies any characterization thereof by Plaintiff.

129. To the extent the allegations in Paragraph 129 are directed at Merck, Merck denies them. Otherwise, Merck lacks knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 129. Merck refers to the referenced statute for its complete and accurate contents and denies any characterization thereof by Plaintiff.

130. To the extent the allegations in Paragraph 130 are directed at Merck, Merck denies them, except that Merck admits it provided certain information requested on behalf of the Senate Finance Committee. To the extent that Plaintiff purports to reference a letter, Merck refers to the letter for its complete and accurate terms and denies any characterizations thereof by Plaintiff.

131. To the extent the allegations in Paragraph 131 refer to statutes, regulations or reports, those sources speak for themselves, and Merck denies any characterizations thereof by Plaintiff.

132. To the extent the allegations in Paragraph 132 are directed at Merck, Merck denies them.

133. To the extent the allegations in Paragraph 133 are directed to Merck, Merck denies them.

134. To the extent the allegations in Paragraph 134 are directed at Merck, Merck denies them. To the extent Paragraph 134 purports to quote portions of the transcript of a congressional hearing, Merck refers to the transcript for complete and accurate testimony in context and denies any characterizations thereof by Plaintiff. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 134.

135. To the extent the allegations in Paragraph 135 are directed at Merck, they are denied. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 135.

136. Merck admits that its standard terms and conditions and certain of its contracts contain confidentiality provisions and that Merck offers discounts to certain of its customers. Merck further avers that its agreements expressly provide that providers should comply with Medicaid reporting obligations. To the extent the other allegations of Paragraph 136 are directed to Merck, they are denied. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 136.

137. To the extent the allegations in Paragraph 137 are directed at Merck, Merck denies them, except Merck admits that different types of customers may be offered or may negotiate different pricing terms for Merck drugs. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 137.

138. To the extent the allegations in Paragraph 138 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form

a belief as to the truth of the allegations in Paragraph 138. With respect to allegations in Paragraph 138 purporting to quote from the transcript of a congressional hearing, Merck refers to the transcript for context and the complete and accurate terms thereof, and denies any characterization thereof by Plaintiff.

139. To the extent the allegations in Paragraph 139 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 139. With respect to allegations in Paragraph 139 purporting to quote from the transcript of a congressional hearing, Merck refers to the transcript for context and the complete and accurate terms thereof, and denies any characterization thereof by Plaintiff.

140. To the extent the allegations in Paragraph 140 are directed at Merck, Merck denies them.

141. To the extent the allegations in Paragraph 141 are directed at Merck, Merck denies them.

142. The allegations in Paragraph 142 relate to other parties, and Merck lacks knowledge or information sufficient to form a belief as to their truth.

143. To the extent the allegations in Paragraph 143 are directed at Merck, Merck denies them. Merck further avers that for years, and at all times relevant to the Complaint, it has been widely known and understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 143 and the exhibit referenced therein.

144. To the extent the allegations in Paragraph 144 are directed at Merck, Merck denies them. Merck specifically denies that it has engaged in any “unlawful and undisclosed manipulation of the price reporting system” or caused the “publication of a false WAC,” AWP, or FUL. Merck avers that, by federal statute and long-standing industry usage, WAC is a list price and does not include discounts, such as for prompt payment. Merck further avers that for years, and at all times relevant to the Complaint, it has been widely known and understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. Merck otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 144.

145. To the extent the allegations in Paragraph 145 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 145.

146. To the extent the allegations in Paragraph 146 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 146.

147. To the extent the allegations in Paragraph 147 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 147.

148. To the extent the allegations in Paragraph 148 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 148.

149. To the extent the allegations in Paragraph 149 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 149.

150. The allegations in Paragraph 150 relate to generic drugs. To the extent such allegations are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 150.

151. To the extent Paragraph 151 is directed to Merck, Merck admits that its drugs may face competition from other drugs that treat the same condition or illness, and that Merck may offer rebates to certain direct or indirect customers, including the State of Iowa, for formulary placement. Merck denies the other allegations of Paragraph 151 as to Merck. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 151.

152. Merck admits that Paragraph 152 purports to quote from a portion of a transcript from a Congressional hearing, refers to the transcript for an accurate and in context transcription, and denies any characterization thereof by Plaintiff. Merck otherwise denies the allegations of Paragraph 152 as to Merck.

153. To the extent the allegations in Paragraph 153 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 153.

154. Merck denies the allegations in Paragraph 154 as to Merck.

155. To the extent the allegations in Paragraph 155 are directed at Merck, Merck denies them. Merck admits that Paragraph 155 purports to quote in part from an

OIG guidance document, refers to the document for an accurate and in context transcription, and denies any characterization thereof by Plaintiff.

156. Merck denies the allegations of Paragraph 156 as to Merck. Merck otherwise lacks knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 156.

157. To the extent the allegations in Paragraph 157 are directed at Merck, Merck denies them. Merck admits that Paragraph 157 purports to quote in part from an OIG guidance document, refers to the document for an accurate and in context transcription, and denies any characterization thereof by Plaintiff.

158. To the extent the allegations in Paragraph 158 are directed at Merck, Merck denies them.

159. Merck admits that it participates in the federal Medicaid rebate program, and otherwise denies the allegations of Paragraph 159.

160. Merck denies the allegations of Paragraph 160 as to Merck. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 160 as to Iowa Medicaid's obligations and as to other defendants.

161. Merck denies the allegations of Paragraph 161 as to Merck. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 161 as to Iowa Medicaid and as to other defendants.

162. Merck denies the allegations of Paragraph 162 as to Merck. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 162 as to Iowa Medicaid and as to other defendants.

163. Merck admits that certain of its products are sold to or reimbursed by public entities, and avers that the terms and conditions of such sales or reimbursements vary. Merck denies that it submits false or inflated pricing information. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 163.

164. Merck denies the allegations of Paragraph 164 as to Merck. Merck further denies that Paragraph 164 fairly or accurately summarizes the relevant law.

165. Merck denies the allegations of Paragraph 165 as to Merck. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 165.

166. To the extent the allegations in Paragraph 166 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 166.

167. To the extent that the allegations in Paragraph 167 are directed at Merck, Merck denies them. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegation that the “Iowa Medicaid Program spent over \$1.6 billion for defendants’ drugs between 1992 and 2005 alone.”

168. To the extent that the allegations in Paragraph 168 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 168.

169. To the extent that the allegations in Paragraph 169 are directed at Merck, Merck denies them.

170. To the extent that the allegations in Paragraph 170 are directed at Merck, Merck denies them.

171. To the extent that the allegations in Paragraph 171 are directed at Merck, Merck denies them.

172. With respect to the allegations in Paragraph 172, Merck admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein as to Merck. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 172.

173. With respect to the allegations in Paragraph 173, Merck admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein as to Merck. To the extent the remaining allegations in Paragraph 173 or Exhibit B are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 173.

174. With respect to the allegations in Paragraph 174, Merck states that none of the Merck drugs purportedly identified in Exhibit B to the Complaint is alleged to be the subject of FUL fraud. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 174.

175. With respect to the allegations in Paragraph 175, Merck denies the accuracy of the data listed in Exhibit B to the Complaint. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 175.

176. With respect to the allegations in Paragraph 176, Merck denies that it “submit[ed] false and inflated reimbursement price information.” Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 176.

177. To the extent the allegations in Paragraph 177 or Exhibit B are directed at Merck, Merck denies them.

178. To the extent the allegations in Paragraph 178 are directed at Merck, Merck denies them.

179. To the extent the allegations in Paragraph 179 are directed at Merck, Merck denies them, except Merck admits that it contracted with certain purchasers and that such contracts sometimes included discounts for certain drugs. Merck avers that the terms and conditions of such contracts varied and denies they are accurately summarized in Paragraph 179.

180. Paragraph 180 and Exhibit A referenced therein refer to NDCs and expenditures, which Plaintiff claims are at issue. Merck denies that any Merck NDCs are properly at issue, further denies that Plaintiff purports to allege “FUL fraud” for any Merck drug, and lacks knowledge or information sufficient to form a belief as to the truth of the alleged expenditures for Merck drugs. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

181-455. The allegations in Paragraphs 181 through 455 are directed to other Defendants and require no response from Merck. To the extent a response is deemed to

be required, Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181 through 455.

456. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Iowa Medicaid's expenditures as alleged in Paragraph 456 and Exhibits A and B. Merck denies that Plaintiff has asserted any FUL fraud claims against Merck and denies that Iowa is entitled to any relief against Merck.

457. Merck denies the allegations of Paragraph 457.

458. Merck admits that it has been the subject of investigations by the government entities identified in Paragraph 458, and denies each and every remaining allegation in Paragraph 458.

459. Merck admits that it has responded to information requests on behalf of the Senate Finance Committee. Merck further avers that the determination of Best Price and the nominal price exception are complex, vary drug by drug, and are made pursuant to statutes, regulations, and regulatory guidance that have changed over time. Merck otherwise denies the allegations of Paragraph 459.

460. Merck denies the allegations of Paragraph 460.

461. Merck admits that Paragraph 461 purports to report allegations that have been made in lawsuits and newspapers, denies that they are accurately summarized in Paragraph 461, and refers to the source materials for the complete context and content thereof.

462. Merck avers that this drug is not at issue pursuant to the Court's prior rulings and decisions. To the extent that any response is required, Merck admits that Paragraph 462 and the footnote thereto purports to report allegations in a lawsuit, avers

that they are not completely or accurately summarized in Paragraph 462, and refers to the pleadings in the action for the complete context and contents thereof.

463. Merck avers that this drug is not at issue pursuant to the Court's prior rulings and decisions. To the extent that any response is required, Merck denies that it calculates AWP, further denies that Plaintiff has alleged spreads for Pepcid ® 20 mg for those years in Exhibit B-22, and avers that the Medicaid rebate statutes, regulations, and regulatory guidance relating to the calculation of Best Price are complex, that the calculations vary from drug to drug, and have changed over time.

464. Merck avers that this drug is not at issue pursuant to the Court's prior rulings and decisions. Otherwise, Merck is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 464 and on that basis denies the allegations.

465. Merck denies the allegations of Paragraph 465, and avers that the Medicaid rebate statutes, regulations, and regulatory guidance relating to the calculation of AMP and Best Price are complex, that the calculations vary from drug to drug, and have changed over time.

466. Merck admits that Paragraph 466 purports to summarize allegations in another action, denies that the summary is accurate or complete, and refers to the pleadings in the referenced action for the full and complete contents and context.

467-613. The allegations in Paragraphs 467 through 613 are directed to other Defendants and require no response from Merck. To the extent a response is deemed to be required, Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 467 through 613.

614. To the extent the allegations in Paragraph 614 are directed at Merck, Merck denies them. Merck lacks knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa's Medicaid program "spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992 through 2005 alone."

615. To the extent the allegations in Paragraph 615 are directed at Merck, Merck denies them. Merck otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 615.

616. To the extent the allegations in Paragraph 616 are directed at Merck, Merck denies them.

617. To the extent the allegations in Paragraph 617 are directed at Merck, Merck denies them.

618. To the extent the allegations in Paragraph 618 are directed at Merck, Merck denies them.

619. To the extent the allegations in Paragraph 619 are directed at Merck, Merck denies them.

620. To the extent the allegations in Paragraph 620 are directed at Merck, Merck denies them.

621. To the extent the allegations in Paragraph 621 are directed at Merck, Merck denies them.

622. To the extent the allegations in Paragraph 622 are directed at Merck, Merck denies them.

623. To the extent the allegations in Paragraph 623 are directed at Merck, Merck denies them.

624. To the extent the allegations in Paragraph 624 are directed at Merck, Merck denies them.

625. To the extent the allegations in Paragraph 625 are directed at Merck, Merck denies them.

626. To the extent the allegations in Paragraph 626 are directed at Merck, Merck denies them.

627. To the extent the allegations in Paragraph 627 are directed at Merck, Merck denies them.

628. To the extent the allegations in Paragraph 628 are directed at Merck, Merck denies them.

629. To the extent the allegations in Paragraph 629 are directed at Merck, Merck denies them.

630. To the extent the allegations in Paragraph 630 are directed at Merck, Merck denies them. To the extent the allegations in Paragraph 630 purport to quote *The Pink Sheet*, Merck refers to the document for its complete and accurate contents and denies any characterizations thereof by Plaintiff.

631. To the extent the allegations in Paragraph 631 are directed at Merck, Merck denies them.

632. To the extent the allegations in Paragraph 632 are directed at Merck, Merck denies them.

COUNT I

**VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8
(FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

633. In response to Paragraph 633, Merck repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 632.

634-642. To the extent the allegations in Paragraphs 634 through 642 are directed at Merck, Merck states that the Court has dismissed the claim to which these allegations relate. To the extent that any response is required, Merck denies the allegations as to itself. To the extent the allegations in Paragraphs 634 through 642 are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a belief as to their truth.

COUNT II

BREACH OF CONTRACT

643. In response to Paragraph 643, Merck repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 642.

644 - 651. To the extent the allegations in Paragraphs 644 through 651 are directed at Merck, Merck states that the Court has dismissed the claim to which these allegations relate. To the extent that any response is required, Merck denies the allegations as to itself. To the extent the allegations in Paragraphs 644 through 651 are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a belief as to their truth.

COUNT III

**IOWA CONSUMER FRAUD ACT
(Iowa Code § 714.16)**

652. In response to Paragraph 652, Merck repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 651.

653. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at Merck, Merck denies them. To the extent the allegations in Paragraph 653 are directed at parties other than Merck, Merck lacks knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

654. To the extent the allegations in Paragraph 654 and the sub-parts thereto are directed at Merck, Merck denies them. To the extent the allegations in Paragraph 654 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied.

655. To the extent the allegations in Paragraph 655 are directed at Merck, Merck denies them.

656. To the extent the allegations in Paragraph 656 are directed at Merck, Merck denies them. Merck refers to the cited statutes and interpretative law, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 656 contain legal conclusions, no response is required.

657. To the extent the allegations in Paragraph 657 are directed at Merck, Merck denies them.

COUNT IV

FRAUD

658. In response to Paragraph 658, Merck repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 657.

659. To the extent the allegations in Paragraph 659 and the exhibits referenced therein are directed at Merck, Merck denies them.

660. To the extent the allegations in Paragraph 660 are directed at Merck, Merck denies them.

661. To the extent the allegations in Paragraph 661 are directed at Merck, Merck denies them.

662. To the extent the allegations in Paragraph 662 are directed at Merck, Merck denies them.

COUNT V

UNJUST ENRICHMENT

663. In response to Paragraph 663, Merck repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

664. To the extent the allegations in Paragraph 664 are directed at Merck, Merck denies them.

665. To the extent the allegations in Paragraph 665 are directed at Merck, Merck denies them.

666. To the extent the allegations in Paragraph 666 are directed at Merck, Merck denies them.

PRAYER FOR RELIEF

667-675. Merck denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667 through 675 of the Complaint. Merck reserves its right to a jury trial to the extent that any claims triable to a jury survive.

AFFIRMATIVE DEFENSES

By alleging the matters set forth below, Merck does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that Plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, Merck alleges as follows:

First Affirmative Defense

Plaintiff fails to state a claim against Merck upon which relief may be granted.

Second Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, because it did not justifiably rely on any alleged misrepresentations or fraud by Merck. Plaintiff knew that providers could obtain Merck drugs at prices below AWP prior to the relevant time period stated in the Complaint.

Third Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Fourth Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by the filed rate doctrine.

Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the state action doctrine.

Sixth Affirmative Defense

To the extent Plaintiff or other entities whose rights are derivative of Plaintiff obtains or is barred from recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Merck based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Merck and/or its agents in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Eighth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction, or otherwise compromised Plaintiff's claims.

Ninth Affirmative Defense

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

Tenth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, ratification, and waiver.

Eleventh Affirmative Defense

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Merck contained in the Complaint.

Twelfth Affirmative Defense

Any and all actions taken by Merck with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

Thirteenth Affirmative Defense

Merck's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff, and any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

Fourteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act. Any statement, acts, or conduct attributed to Merck were not made or done in the conduct of business or commerce or to promote the sale or increase the consumption of goods, were not consumer-oriented, and were not addressed to the public or a substantial number of persons.

Fifteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

Sixteenth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, by Plaintiff's failure to comply with its federal or state statutory and regulatory obligations.

Seventeenth Affirmative Defense

To the extent that any claim against Merck under the Iowa Consumer Fraud Act is found to exist, Merck asserts all defenses available under the Act. Iowa Code Ann. § 714.16.

Eighteenth Affirmative Defense

To the extent that Plaintiff attempts to seek equitable relief against Merck, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

Nineteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Twentieth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Merck after the filing of the Complaint.

Twenty-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by statutory and supplemental rebate agreements.

Twenty-Second Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, due to its failure to join indispensable parties.

Twenty-Third Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

Twenty-Fourth Affirmative Defense

Plaintiff's damages claims against Merck are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and its failure to mitigate damages should proportionately reduce the recovery of Plaintiff and the allocation of any fault, if any exists, attributable to Merck; (2) because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

Twenty-Fifth Affirmative Defense

Merck is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries, or for any overpayments of rebates by Merck or underpayments by Plaintiff for Merck drugs.

Twenty-Sixth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

Twenty-Seventh Affirmative Defense

Plaintiff's claims against Merck are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

Twenty-Eighth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, because they violate Merck's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Twenty-Ninth Affirmative Defense

Plaintiff's claims against Merck are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.

Thirtieth Affirmative Defense

The claims alleged herein, based on the facts alleged, are barred, in whole or in part, by Plaintiff's own negligence or gross negligence and the doctrines of comparative and/or contributory negligence.

Thirty-First Affirmative Defense

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Merck did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

Thirty-Second Affirmative Defense

Plaintiff has failed to exhaust available statutory and administrative remedies.

Thirty-Third Affirmative Defense

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

Thirty-Fourth Affirmative Defense

Plaintiff's claims against Merck are barred because Plaintiff lacks standing or capacity to bring the some or all of the claims asserted against Merck under Iowa law.

Thirty-Fifth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, by the doctrine of voluntary payment.

Thirty-Sixth Affirmative Defense

Plaintiff's claims against Merck for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Thirty-Seventh Affirmative Defense

Plaintiff's claims against Merck for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

Thirty-Eighth Affirmative Defense

Plaintiff's claims against Merck for injunctive relief are barred by the doctrines of *in pari delicto* and/or unclean hands.

Thirty-Ninth Affirmative Defense

Plaintiff's claims against Merck are misjoined with Plaintiff's claims against other Defendants and must be severed.

Fortieth Affirmative Defense

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

Forty-First Affirmative Defense

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Merck: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Merck; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give Merck prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Merck's Due Process rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Merck's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

Forty-Second Affirmative Defense

Plaintiff fails to allege facts or a cause of action against Merck sufficient to support a claim for prejudgment interest or any other relief.

Forty-Third Affirmative Defense

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of Merck as alleged in the Complaint.

Forty-Fourth Affirmative Defense

Plaintiff's claims against Merck are barred because Merck has complied with all applicable laws and regulations of the federal and state governments.

Forty-Fifth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

Forty-Sixth Affirmative Defense

Plaintiff's claims against Merck are barred, in whole or in part, because Merck did not make any false statements to the Plaintiff or its agents. As to any statement asserted against Merck that Plaintiff alleges to be false or misleading, Merck had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Forty-Seventh Affirmative Defense

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against Merck for compensatory damages, restitution, attorneys' fees, enhanced damages, and/or legal fees or costs.

Forty-Eighth Affirmative Defense

Merck adopts by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

Forty-Ninth Affirmative Defense

Merck hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense.

WHEREFORE, Defendant Merck & Co., Inc., demands: (1) that the Complaint be in all respects dismissed with prejudice as to Merck; (2) its costs and expenses of defending this action; and (3) such other and further relief as the Court may deem just and proper.

Dated: September 18, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. TO THE STATE OF IOWA'S COMPLAINT was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ Robert B. Funkhouser
Robert B. Funkhouser